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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,614	03/01/2000	GAIL PETUNA RISBRIDGER	229752000800	6186

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EXAMINER
NICKOL, GARY B

ART UNIT	PAPER NUMBER
1642	12

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/402,614	RISBRIDGER ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 40-67* is/are pending in the application.

4a) Of the above claim(s) *1-26,40-57,59,61 and 64-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58, 60, 62-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Election filed September 10, 2001 (Paper No. 11) in response to the Office Action of March 9, 2001 is acknowledged and has been entered. Claims 1-26, and 40-67 are pending in the application. Claims 1-26, 40-57, 59, 61, 64-67 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 58, 60, and 62-63 are currently under prosecution.

Applicant's election with traverse of Group 10, claims 58, 60-63 in Paper No 11 is acknowledged with the species election to the αC-inhibin or isoform thereof (Claim 62). The traversal is on the ground(s) that Alvardo *et al.* does not disclose the invention in issue because applicants submit that the technical feature which links ALL these claims and defines a contribution over the prior art is the determination that the modulation of inhibin levels can be related to the development of prostate cancer. Applicants further note that all of the claims in each of Groups 10-17 specifically relate to a method of diagnosing prostate cancer or predisposition thereto based on changes in the level of expression of inhibin and that almost all of the claims of groups 1-9 are specific to this feature. These arguments have been considered but are not found persuasive. Independent Claim 1 does not include a contribution over the prior art because it is not drawn to the determination that the modulation of inhibin levels can be related to the development of prostate cancer. Claim 1 is only drawn to modulating cell growth in a mammal by administering an effective amount of an agent which modulates the expression of a genetic sequence encoding inhibin. With regards to dependent claims, unity of invention has to be considered in the first place only in relation to the independent claims in an

international application and not the dependent claims. For these reasons the restriction requirement under 35 U.S.C. 121 and 372 is deemed to be proper and is therefore made FINAL.

Specification

The specification is objected to for the following reason: The specification on page 1 should be amended to reflect the priority status of the present application. Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Since the application claims the benefit of an international application, the first sentence of the specification must include an indication of whether the international application was published under PCT Article 21(2) in English (regardless of whether benefit for such application is claimed in the application data sheet).

Claim Objections

Claim 63 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim 58 is objected to for reciting "or predisposition to prostate cancer" and "being predisposed to prostate cancer" as it is drawn to a non-elected group.

Claim 60 is objected to for reciting "or 59" as it is drawn to a non-elected group.

Claim 62 is objected to for reciting "αC isoform thereof" as it renders the claim grammatically incorrect.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58, 60, and 62-63 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: In claim 58 there is no relationship between down-regulation of inhibin and that which is considered to be a normal/standard amount of inhibin. Thus, a comparison to a controlled normal mammalian prostate appears essential.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58, 60, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Teni *et al.* (Clinical Chemistry, Volume 35, No. 7, pages 1376-1379, 1989).

The claims are drawn to a method of screening for a mammal having prostate cancer comprising screening for the down-regulation of inhibin protein levels in said mammal wherein

the down-regulation of said inhibin protein levels is indicative of said mammal having already developed prostate cancer (Claim 58); wherein said inhibin is α-inhibin (Claim 60); wherein said α-inhibin is αC-inhibin or an isoform thereof (Claim 62).

Teni *et al.* teach a method of screening for a mammal having prostate cancer comprising screening for the down-regulation of prostatic inhibin-like peptide levels in said mammal wherein the down-regulation of said peptide is indicative of said mammal having already developed prostate cancer (see Abstract and Figure 3). Due to the broadly defined definition of inhibin (specification, page 7, lines 5-10), it is assumed for examination purposes that inhibin-like peptide is the same inhibin as that which is claimed. Further, although the reference does not specifically teach that α-inhibin or αC-inhibin was screened, inherently α-inhibin or αC-inhibin was screened since the structure of the inhibin polypeptides are heterodimeric in nature wherein such polypeptides exist as Inhibin A (α:βA) and Inhibin B (α:βB) (see specification, page 1, lines 26-27). Thus, antibodies to inhibin (Teni *et al.* , page 1376, 2nd column) would inherently detect the heterodimeric polypeptides.

The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 58, 60, 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ying *et al.* (Life Sci. Volume 60, Number 6, pages 397-401, January 1997, IDS, #47) and Teni *et al.* (Clinical Chemistry, Volume 35, No. 7, pages 1376-1379, 1989).

The claims are drawn to a method of screening for a mammal having prostate cancer comprising screening for the down-regulation of inhibin protein levels in said mammal wherein the down-regulation of said inhibin protein levels is indicative of said mammal having already developed prostate cancer (Claim 58); wherein said inhibin is α-inhibin (Claim 60); wherein said α-inhibin is αC-inhibin or an isoform thereof (Claim 62); wherein said downregulation is absence (Claim 63).

1. Ying *et al.* teach a method of detecting inhibin protein in normal mammalian prostate using specific polyclonal antibodies raised against α-inhibin (page 398, 2nd column, 3rd paragraph, and abstract). Ying *et al.* further teach that it is of particular interest that the distribution of inhibin reactive cells was only identified in normal rat prostate cells. This observation, they teach, is different from that in human prostate cancer cells which have no inhibin reactive cells (page 400, last paragraph).
2. Teni *et al.* teach a method of screening for a mammal having prostate cancer comprising screening for the down-regulation of inhibin protein levels in said mammal wherein the down-regulation of said inhibin protein levels is indicative of said mammal having already developed prostate cancer as set forth above.
3. Ying *et al.* do not specifically teach screening for prostate cancer by detecting of αC-inhibin or an isoform thereof.

It would have been *prima facia* obvious to one of ordinary skill in the art at the time the invention was made to modulate the method of Ying *et al.* so as to screen for prostate cancer using the specific polyclonal antibodies raised against α-inhibin since Teni *et al* teach the successful screening of prostate cancer comprising screening for the down-regulation of inhibin protein levels. One would have been motivated to do so because Ying *et al.* specifically recognize that there is an difference between the levels of α-inhibin in rat prostate as compared to the absence of inhibin in human prostate cancers, and furthermore, it was known in the art at the time the invention was made that men with prostate cancer had lower levels of inhibin protein versus age-matched normal controls (Teni *et al.* , abstract and Figure 3). Thus, one of

ordinary skill in the art would have had a reasonable expectation of success in screening for mammalian prostate cancer by comparing the presence of α-inhibin in mammals without prostate cancer versus the absence of α-inhibin in mammals with prostate cancer.

Although the reference does not specifically teach the screening of αC-inhibin or an isoform thereof, the claimed peptide appears to be detected in the prior art of Ying *et al.* , absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
March 21, 2002

ANTHONY C. CAPUTA
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